APR 12 2006

K052243

# 510(k) Summary

## (1) Contact Information

This 510(k) is being submitted by Joseph Azary on behalf of ProAct.

**Submitter / Regulatory Consultant:** Joseph Azary, 543 Long Hill Avenue, Shelton, CT 06484, Tel: 203-944-9320, Fax: 203-944-9317

**Applicant / Sponsor:** ProAct Inc. (Professional Advanced Compression Therapy Inc.), 1 Stone River Road, Laurel Springs, New Jersey 08021, FDA Establishment Registration pending.

## (2) Device Information

The device is classified as Class II under IRP and JOW, 21 CFR 890.5650 and 21 CFR 870.5800.

The ProAct 1 or ProAct with gel device is a gradient sequential compression device used in the treat ment of lymphedema.

The ProAct with gel is a modification to the ProAct 1 device that received FDA marketing clearance under 510(k) K003909.

The ProAct with gel uses the same powered control device that delivers gradient sequential compression pressure to the chambered compressible limb sleeves. The device is composed of three components:

- Lightweight, portable control unit
- Compressible limb sleeves with gel in 3 sizes for arms and legs (Brookwood 70 denier MD Nylon and DAF Breathable 270 Nylon)
- Pneumatic connecting tubes

The control unit specifications and limb sleeve specifications have been included in Annex 1.

- The subject device includes sleeves with Nosocryl D60 gel in the chambers.

The gel was added to address market requests.

The gel does not make direct contact with the patient. The gel will be enclosed within the Nylon cham ber. In the event the Nosocryl material leaked it is believed to have minimal safety concerns. Nosocryl is a super absorbent polymer material that has been used in disposable diapers over the last 20 years and also in feminine care products, adult incontinence pads, and in absorbent pads used in food package ing. Nosocryl has the following toxicological characteristics.

- Practically no harm to animals during acute toxicity testing.
- Practically no harm to animals during skin contact and eye contact testing.
- The material is not a skin sensitizer.
- Studies of prolonged inhalation in animals have not shown systemic effects.
- Experimental data found the material not to be genotoxic.

(3) **Trade or Proprietary Name:** ProAct with Gel or ProAct I

**Common, Usual, and Classification Name:**

- Gradient Sequential Compression Pump
- Powered Inflatable Tube Massager.

**(4) Predicate Devices:**

The predicate devices are identified as the following:

ProAct I – 510(k) K003909

The difference with the ProAct with gel is as follows:

- The sleeves now contain chambers with Nosocryl D60 gel.

The material is non-toxic and has been used for other medical applications.

(5) **Intended Use:**

The ProAct with Gel is a prescriptive device indicated for:

- Lymphedema – primary and secondary
- Prevention of venous stasis
- Prevention of Deep Vein Thrombosis (DVT)
- Edema following trauma and sports injuries
- Post immobilization edema

**(6) Technological Characteristics:** The technological characteristics of the device remain the same. The gel is added to the chambers. The indications for use, power unit, and features of the device remain the same.

**(7) Conclusion:** We believe the differences are minor and conclude that the subject device is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 12 2006

Azary Technologies, LLC
c/o Mr. Joseph M. Azary III
President
543 Long Hill Avenue
Shelton, CT 06484

Re: K052243
ProAct with gel / ProAct 1
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible limb sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: January 12, 2006
Received: January 17, 2006

Dear Mr. Azary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known):

Device Name: ProAct with gel / ProAct 1

Indications For Use:

The ProAct with Gel is a prescriptive device indicated for:

- Lymphedema – primary and secondary
- Prevention of venous stasis
- Prevention of Deep Vein Thrombosis (DVT)
- Edema following trauma and sports injuries
- Post immobilization edema

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

B Limmeiman

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K052243